

We Claim:

1. A pharmaceutical composition comprising:

- (a) a tiotropium salt; and
- (b) an antihistamine,

optionally together with a pharmaceutically acceptable excipient,

the tiotropium salt and the antihistamine optionally in the form of their enantiomers, mixtures of their enantiomers, their racemates, their solvates, or their hydrates.

2. The pharmaceutical composition according to claim 1, wherein the tiotropium salt is a salt with a counter-ion selected from chloride, bromide, iodide, *p*-toluene sulfonate, or methylsulfate.

3. The pharmaceutical composition of claim 2, wherein the counter-ion is bromide.

4. The pharmaceutical composition according to claim 1, wherein the antihistamine is selected from the group consisting of: epinastine, cetirizine, azelastine, fexofenadine, levocabastine, loratadine, mizolastine, ketotifen, emedastine, dimethindene, clemastine, bamipine, dexchlorpheniramine, pheniramine, doxylamine, chlorphenoxamine, dimenhydrinate, diphenhydramine, promethazine, ebastine, desloratadine, and meclozine.

5. The pharmaceutical composition according to claim 2, wherein the antihistamine is selected from the group consisting of: epinastine, cetirizine, azelastine, fexofenadine, levocabastine, loratadine, mizolastine, ketotifen, emedastine, dimethindene, clemastine, bamipine, dexchlorpheniramine, pheniramine, doxylamine, chlorphenoxamine, dimenhydrinate, diphenhydramine, promethazine, ebastine, desloratadine, and meclozine.

6. The pharmaceutical composition according to claim 3, wherein the antihistamine is selected from the group consisting of: epinastine, cetirizine, azelastine, fexofenadine,

levocabastine, loratadine, mizolastine, ketotifen, emedastine, dimethindene, clemastine, bamipine, dexchlorpheniramine, pheniramine, doxylamine, chlorphenoxamine, dimenhydrinate, diphenhydramine, promethazine, ebastine, desloratadine, and meclozine.

7. The pharmaceutical composition according to claim 3, wherein the antihistamine is selected from the group consisting of: epinastine, cetirizine, azelastine, fexofenadine, levocabastine, loratadine, ebastine, desloratadine and mizolastine.

8. The pharmaceutical composition according to claim 1, wherein the weight ratios of the tiotropium salt to the antihistamine are in the range of from 1:300 to 50:1.

9. The pharmaceutical composition according to claim 8, wherein the weight ratios of the tiotropium salt to the antihistamine are in the range of from 1:250 to 40:1.

10. The pharmaceutical composition according to claim 1, wherein the pharmaceutical composition is an inhalable powder, a propellant-containing metering aerosol, or a propellant-free inhalable solution or suspension.

11. The pharmaceutical composition according to claim 1, wherein the pharmaceutical composition further comprises a suitable physiologically acceptable excipient selected from the group consisting of: monosaccharides, disaccharides, oligo- and polysaccharides, polyalcohols, and salts.

12. The pharmaceutical composition according to claim 2, wherein the pharmaceutical composition further comprises a suitable physiologically acceptable excipient selected from the group consisting of: monosaccharides, disaccharides, oligo- and polysaccharides, polyalcohols, and salts.

13. The pharmaceutical composition of claim 11, wherein the excipient has a maximum average particle size of up to 250 μm .

14. The pharmaceutical composition of claim 12, wherein the excipient has a maximum average particle size of up to 250 μm .
15. The pharmaceutical composition of claim 13, wherein the excipient has a maximum average particle size of between 10 μm and 150 μm .
16. The pharmaceutical composition of claim 14, wherein the excipient has a maximum average particle size of between 10 μm and 150 μm .
17. A capsule containing a pharmaceutical composition according to claim 1 in the form of an inhalable powder.
18. A capsule containing a pharmaceutical composition according to claim 2 in the form of an inhalable powder.
19. A capsule containing a pharmaceutical composition according to claim 3 in the form of an inhalable powder.
20. A capsule containing a pharmaceutical composition according to claim 4 in the form of an inhalable powder.
21. A capsule containing a pharmaceutical composition according to claim 5 in the form of an inhalable powder.
22. A capsule containing a pharmaceutical composition according to claim 6 in the form of an inhalable powder.
23. A capsule containing a pharmaceutical composition according to claim 7 in the form of an inhalable powder.

24. A capsule containing a pharmaceutical composition according to claim 8 in the form of an inhalable powder.

25. A capsule containing a pharmaceutical composition according to claim 9 in the form of an inhalable powder.

26. A capsule containing a pharmaceutical composition according to claim 10 in the form of an inhalable powder.

27. A capsule containing a pharmaceutical composition according to claim 11 in the form of an inhalable powder.

28. A capsule containing a pharmaceutical composition according to claim 12 in the form of an inhalable powder.

29. A capsule containing a pharmaceutical composition according to claim 13 in the form of an inhalable powder.

30. A capsule containing a pharmaceutical composition according to claim 14 in the form of an inhalable powder.

31. A capsule containing a pharmaceutical composition according to claim 15 in the form of an inhalable powder.

32. A capsule containing a pharmaceutical composition according to claim 16 in the form of an inhalable powder.

33. A pharmaceutical composition according to claim 1, wherein the pharmaceutical composition is a propellant-containing inhalable aerosol and the tiotropium salt and the antihistamine are in dissolved or dispersed form.

34. The pharmaceutical composition according to claim 33, wherein the propellant-containing inhalable aerosol comprises a propellant gas selected from hydrocarbons and halohydrocarbons.

35. The pharmaceutical composition according to claim 33, wherein the propellant-containing inhalable aerosol comprises a propellant gas selected from the group consisting of: *n*-propane; *n*-butane; isobutane; and chlorinated and/or fluorinated derivatives of methane, ethane, propane, butane, cyclopropane, and cyclobutane.

36. The pharmaceutical composition according to claim 34, wherein the propellant gas is TG134a, TG227, or a mixture thereof.

37. The pharmaceutical composition according to claim 33, further comprising at least one of a cosolvent, stabilizer, surfactant, antioxidant, lubricant, or means for adjusting the pH of the composition.

38. The pharmaceutical composition according to claim 34, further comprising at least one of a cosolvent, stabilizer, surfactant, antioxidant, lubricant, or means for adjusting the pH of the composition.

39. The pharmaceutical composition according to claim 35, further comprising at least one of a cosolvent, stabilizer, surfactant, antioxidant, lubricant, or means for adjusting the pH of the composition.

40. The pharmaceutical composition according to claim 36, further comprising at least one of a cosolvent, stabilizer, surfactant, antioxidant, lubricant, or means for adjusting the pH of the composition.

41. The pharmaceutical composition according to claim 33, wherein the amount of the tiotropium salt or the antihistamine is up to 5 wt.% of the pharmaceutical composition.

42. A pharmaceutical composition according to claim 1, wherein the pharmaceutical composition is propellant-free inhalable solution or suspension that further comprises a solvent selected from water, ethanol, or a mixture of water and ethanol.

43. The pharmaceutical composition according to claim 42, wherein the pH is between 2 and 7.

44. The pharmaceutical composition according to claim 43, wherein the pH is between 2 and 5.

45. The pharmaceutical composition according to claim 42, wherein the pH of the pharmaceutical composition is adjusted by means of one or more acids selected from the group consisting of: hydrochloric acid, hydrobromic acid, nitric acid, sulfuric acid, ascorbic acid, citric acid, malic acid, tartaric acid, maleic acid, succinic acid, fumaric acid, acetic acid, formic acid, and propionic acid.

46. The pharmaceutical composition according to claim 42, further comprising other co-solvents or excipients.

47. The pharmaceutical composition according to claim 45, further comprising other co-solvents or excipients.

48. The pharmaceutical composition according to claim 46, wherein the co-solvent is selected from the group consisting of alcohols, glycols, polyoxyethylene alcohols, and polyoxyethylene fatty acid esters.

49. The pharmaceutical composition according to claim 46, wherein the co-solvent is selected from the group consisting of: isopropyl alcohol, propylene glycol, polyethylene glycol, polypropylene glycol, glycol ether, and glycerol.

50. The pharmaceutical composition according to claim 46, wherein the excipient is selected from the group consisting of: surfactants, stabilizers, complexing agents, antioxidants, preservatives, flavorings, pharmacologically acceptable salts, and vitamins.

51. The pharmaceutical composition according to claim 50, wherein the excipient is selected from the group consisting of: edetic acid, a salt of edetic acid, ascorbic acid, vitamin A, vitamin E, tocopherols, cetyl pyridinium chloride, benzalkonium chloride, benzoic acid, and benzoate salts.

52. A pharmaceutical composition consisting essentially of:

- (a) a tiotropium salt;
- (b) an antihistamine;
- (c) a solvent;
- (d) benzalkonium chloride; and
- (e) sodium edetate.

53. A pharmaceutical composition consisting essentially of:

- (a) a tiotropium salt;
- (b) an antihistamine;
- (c) a solvent; and
- (d) benzalkonium chloride.

54. A method of treating allergic or non-allergic rhinitis in a patient in need of such treatment, the method comprising administering to the patient a therapeutically effective amount of the pharmaceutical composition according to one of claims 1 to 12.

55. A kit comprising one or more unit dosage containers containing a pharmaceutical composition, each unit dosage container containing a pharmaceutical composition comprising:

- (a) a tiotropium salt; and
- (b) an antihistamine,

each optionally together with a pharmaceutically acceptable excipient,

the tiotropium salt and the antihistamine optionally in the form of their enantiomers, mixtures of their enantiomers, their racemates, their solvates, or their hydrates.

56. The kit according to claim 55, further comprising instructions with directions for using the kit.

57. A kit comprising:

- (a) a first container containing a first pharmaceutical formulation comprising a tiotropium salt; and
- (b) a second container containing a second pharmaceutical formulation comprising a comprising an antihistamine,

each container each optionally further containing a pharmaceutically acceptable excipient, the tiotropium salt and the antihistamine optionally in the form of their enantiomers, mixtures of their enantiomers, their racemates, their solvates, or their hydrates.

58. The kit according to claim 57, further comprising instructions with directions for using the kit.